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Docket No. 69014-B/GJG/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants	:	Kiran K. Chada et al.	
Serial No.	:	10/768,566	Group Art Unit: 1646
Filed	:	January 29, 2004	Examiner: G. Chandra
For	:	METHODS OF TREATING OBESITY AND METABOLIC DISORDERS RELATED TO EXCESS ADIPOSE TISSUE BY ADMINISTRATION OF S-FRP-5 PEPTIDE	

30 Rockefeller Plaza
New York, New York 10112
February 5, 2009

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO JANUARY 21, 2009 NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

This Communication is submitted in response to the January 21, 2009 Notification of Non-Compliant Appeal Brief issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A copy of the Notification is attached hereto as **Exhibit 1**. Applicants note that an Order Returning Undocketed Appeal to the Examiner was issued January 7, 2009 in connection with the above identified application. The Order specified in a detailed manner the items of non-compliance which are referred to in the January 21, 2009 Notification. A copy of the Order is attached hereto as **Exhibit 2**. A response to the Notification is due February 21, 2009. Accordingly, this response is being timely filed.

The January 21, 2009 Notification indicates that Appellants' Appeal Brief filed December 11, 2007 (received by the U.S. Patent and Trademark Office on December 13, 2007) is defective for the following reasons:

(a) the brief does not contain, inter alia, "a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number";

(b) the brief does not contain a concise statement of each ground of rejection presented for review and that "the grounds of rejection for review should list the same rejections as those set forth in the Examiner's Office Action".

The Notice also states that an amended Appeal Brief must be filed within the relevant time limit to avoid dismissal of the Appeal.

In response, Appellants enclose herewith as **Exhibit 3** an amended Appeal Brief in compliance with 37 C.F.R. §41.37 which specifically includes amendments to address points (a) and (b) enumerated above. Appellants specifically note the following:

In the "Summary of Claimed Subject matter" section on page 9 of the enclosed Brief the independent claims 1 and 17 on appeal are identified and mapped by page and line number to the specification in the enclosed amended Brief.

In the "Grounds of Rejection to be Reviewed on Appeal" section on page 10 of the enclosed amended Brief all of the claims on appeal rejected under 35 U.S.C. 102(e), i.e claims 1, 8, 9 and 17-19 are identified. The Final Office Action issued May 16, 2006 states that claims 1-9 are rejected under 35 U.S.C. 112, Second Paragraph, and that claims 1-6, 8, 9 and 17 are rejected under 35 U.S.C. 112, enablement and under 35 U.S.C. 112, written description. However, the Advisory Action issued March 5, 2007 in connection with the above identified application stated that applicants response filed January 26, 2007 had overcome all rejections apart from the 35 U.S.C. 102(e) rejection. Accordingly, only the 35 U.S.C. 102(e) rejection is referred to in the Grounds of Rejection to be Reviewed on Appeal" section on page 10 of the enclosed amended Brief.

Additionally, although not noted in the January 21, 2009 Notification, the January 7, 2009 Order notes that the Claims Appendix should be a clean copy of the claims. Accordingly, the Claims Appendix of the enclosed amended Brief recites a clean copy of the claims.

Appellants also note that the enclosed amended Appeal Brief refers to an enclosed check in the amount of $1295.00 covering (i) the fee for filing a brief in support of an appeal under 37 C.F.R. §41.20(b)(2); (ii) the fee for filing a request for an oral hearing before the Board of Patent Appeals and Interferences in an appeal under 37 C.F.R. §41.20(b)(3); and (iii) the fee for a three-month extension of time for a small entity. Appellants further note that such a check was *previously* enclosed with the Appeal Brief as filed on October 15, 2007 and was received by the U.S. Patent and Trademark

Office. Accordingly, a second check in this amount has not been included with the enclosed amended Appeal Brief.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Appellants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125

Respectfully submitted,

Gary J. Gershik
Registration No. 39,992
Attorney for Appellants
Cooper & Dunham LLP
30 Rockefeller Plaza,
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New York, New York 10112
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Gary J. Gershik 2/5/09

Gary J. Gershik Date
Reg. No. 39,992

EXHIBIT 1

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No.	Applicant(s)	
	10/768,566	CHADA ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *13 December 2007* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

NON COMPLIANT Amendment Due 2-21
2MO 3-21
3MO 4-21
4MO 5-21
5MO 6-21
6MO 7-2

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☒ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☒ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

Summary of claimed subject matter must identify and map all independent claims on appeal (1 and 17) to specification by page and line number.

The grounds of rejection for review, should list the same rejections as those set forth in the examiner's office action .

S Coates

SHARMALLA COATES
SUPERVISORY PATENT APPEAL CENTER SPECIALIST

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,566	01/29/2004	Kiran K. Chada	69014-B/GJG	6434

7590 01/21/2009

EXAMINER	

Gary J. Gershik
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 11036

ART UNIT	PAPER NUMBER

DATE MAILED: 01/21/2009

Please find below and/or attached an Office communication concerning this application or proceeding.

EXHIBIT 2

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KIRAN K. CHADA,
ROLAND CHOUINARD, HENA ASHAR
and
ABU SAYED

Application 10/768,566
Technology Center 1600

Mailed: January 7, 2009

Before PAMELA S. BENNETT, *Review Team Paralegal.*

BENNETT, *Review Team Paralegal.*

ORDER RETURNING UNDOCKETED APPEAL TO EXAMINER

This application was electronically received at the Board of Patent Appeals and Interferences on August 18, 2008. A review of the application revealed that it is not ready for docketing as an appeal. Accordingly, the application is herewith being returned to the Examiner to address the following matters requiring attention prior to docketing.

APPEAL BRIEF, SUMMARY OF CLAIMED SUBJECT MATTER

Appellants filed an Appeal Brief dated December 13, 2007. The Appeal Brief is not in compliance with 37 CFR § 41.37(c) effective September 13, 2004.

According to 37 CFR § 41.37(c) (v) (2006), the Appeal Brief must include the following:

> (v) ***Summary Of Claimed Subject Matter***. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

The "Summary of claimed subject matter" appearing on page 9 of the Appeal Brief is deficient because it does not separately map the independent claims (1, 17) to the specification. Correction is required.

APPEAL BRIEF, GROUNDS OF REJECTION

According to 37 CFR § 41.37(c)(1)(vi), the Appeal Brief must include the following:

> (vi) *Grounds of rejection to be reviewed on appeal.* A concise statement of each ground of rejection presented for review.

The "Grounds of rejection to be reviewed on appeal" appearing on page 10 of the Appeal Brief is deficient because it does not include a listing of the claims involved in the rejection. Correction is required.

APPEAL BRIEF, CLAIMS APPENDIX

According to 37 CFR § 41.37(c)(1)(viii), the Appeal Brief must include the following:

> (viii) *Claims appendix.* An appendix containing a copy of the claims involved in the appeal

Section 1205.02 of the *Manual of Patent Examining Procedure* (MPEP) (Eighth Edition, Rev. 6, September 2007), states that the copy of the claims should be a clean copy and should not include any markings such as brackets or underlining except for claims in a reissue application. Correction is required.

CONCLUSION

Accordingly, it is **ORDERED** that the application is returned to the Examiner:

1) to hold the Appeal Brief filed December 13, 2007 defective, as required by 37 CFR § 41.37(d);

2) to notify Appellants to submit a revised Appeal Brief which corrects the "Summary of claimed subject matter," "Grounds of rejection to be reviewed on appeal," and "Claims appendix";

3) to acknowledge and consider the revised Appeal Brief; and

4) for such further action as may be required.

If there are any questions pertaining to this Order, please contact the Board of Patent Appeals and Interferences at 571-272-9797.

PSB

Gary J. Gershik
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1185 Avenue of the Americas
New York, NY 11036

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,566	01/29/2004	Kiran K. Chada	69014-B/GJG	6434

7590 01/07/2009

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

EXHIBIT 3

Docket No. 69014-B/GJG/BJA

Oral Hearing Requested

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants	:	Kiran K. Chada et al.	
Serial No.	:	10/768,566	Group Art Unit: 1646
Filed	:	January 29, 2004	Examiner: G. Chandra
For	:	METHODS OF TREATING OBESITY AND METABOLIC DISORDERS RELATED TO EXCESS ADIPOSE TISSUE BY ADMINISTRATION OF S-FRP-5 PEPTIDE	

30 Rockefeller Plaza
New York, New York 10112
FILED October 15, 2007
AMENDED December 10, 2007
AMENDED February 5, 2009

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF
AND REQUEST FOR ORAL HEARING AND PETITION FOR THREE-MONTH EXTENSION OF TIME

This appeal was taken from the Examiner's final rejection of claims 1-9 and 17 in the Final Office Action dated January 10, 2007 issued in connection with the above-identified application. The required fee for filing a brief in support of an appeal under 37 C.F.R. §41.20(b)(2) is TWO HUNDRED AND FIFTY FIVE DOLLARS ($255.00) for a small entity. Appellants also hereby request an oral hearing in connection with this appeal. The required fee for filing a request for an oral hearing before the Board of Patent Appeals and Interferences in an appeal under 37 C.F.R. §41.20(b)(3) is FIVE HUNDRED AND

FIFTEEN DOLLARS ($515.00) for a small entity. Accordingly, a check including these amounts is enclosed.

On May 10, 2007, Appellants mailed a Notice of Appeal and a Petition for One-Month Extension of Time which was received by the U.S. Patent and Trademark Office on May 14, 2007. Appellants' brief on appeal was due July 14, 2007, based on the May 14, 2007 receipt date of appellants' Notice of Appeal (37 C.F.R. § 41.37(a)(1) and M.P.E.P. §1206). Appellants hereby petition for a three-month extension of time. The fee for a three-month extension of time for a small entity is FIVE HUNDRED AND TWENTY FIVE DOLLARS ($525.00) and a check including this amount is enclosed. With a three-month extension of time, a response is now due October 14, 2007. However, since October 14, 2007 falls on a Sunday, a response filed on the next succeeding day which is not a Saturday, Sunday or Federal Holiday, i.e. Monday, October 15, 2007, is considered timely under 37 C.F.R. §1.7. Accordingly, this Appeal Brief is being timely filed.

If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

TABLE OF CONTENTS

1. REAL PARTY IN INTEREST

The owner of the subject application at the time of filing this brief is HM Gene, Inc., a corporation organized under the laws of Delaware and having a place of business at 675 Hoes Lane, Research Tower, Room R-603, Piscataway, NJ, 08854, the assignee of record of the above-identified patent by virtue of an assignment from Kiran K. Chada, Roland Chouinard, Hena Ashar and Md. Abu Sayed recorded on July 28, 2004 with the U.S. Patent and Trademark Office at Reel 015613 Frame 0506, a copy of which is attached hereto as **Exhibit C**.

2. RELATED APPEALS AND INTERFERENCES

None.

3. STATUS OF CLAIMS

Claims 1, 8, 9 and 17-19 as reproduced in clean form in **Claims Appendix A-1** have been entered and finally rejected solely on the ground of anticipation. Accordingly, claims 1, 8, 9 and 17-19 are pending and rejected. Claims 2-7 and 10-16 have previously been cancelled.

4. STATUS OF AMENDMENTS

On January 10, 2007, the date of issuance of the Final Office Action, claims 1-9 and 17 were pending and finally rejected in the subject application.

In their January 26, 2007 Amendment appellants presented for entry an amended claim set, including the cancellation of claims 2-7 without prejudice, the addition of new claims 18 and 19, and the amendment of claims 1 and 17. On April 16, 2007, the Examiner issued an Advisory Action indicating that the set of amended claims would be entered but did not place the subject application in condition for allowance.

5. SUMMARY OF THE CLAIMED SUBJECT MATTTER

The claimed subject matter common to independent claim 1 and dependent claims 8 and 9 is method of reducing the amount of adipose tissue in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide comprises consecutive amino acids having the sequence set forth in SEQ ID NO: 1. The claimed subject matter common to independent claim 17 and dependent claims 18 and 19 is a method of reducing the level of adipose tissue formation in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the level of adipose tissue formation, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide comprises consecutive amino acids having the sequence set forth in SEQ ID NO: 1.

The subject matter of independent claim 1 is supported in the specification at, inter alia, page 7, lines 2-11; page 13, line 30; and page 15, lines 27-28.

The subject matter of independent claim 17 is supported in the specification at, inter alia, page 7, lines 2-11 and page 13, line 30 and original claim 17.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There is one ground of rejection to be reviewed, whether Appellants' now claimed invention, as recited in claims 1, 8, 9 and 17-19, is anticipated under 35 U.S.C. §102(e) by Xu et al., U.S. Patent Application Publication No. 2003/0143610 A1, published July 31, 2003 ("Xu et al.") (**Evidence Appendix B.1**).

7. ARGUMENT

It is the Appellants' position that (i) Xu et al. does not teach all elements of the claimed invention; (ii) Xu et al. does not inherently disclose all elements of the claimed invention; (iii) the requirements for inherent anticipation have not been met in the rejection set forth; and (iv) Xu et al. is not an enabling disclosure for what the Examiner alleged it teaches.

Appellants note that their position iterated in the preceding paragraph applies separately to each of the rejected claims 1, 8, 9 and 17-19. Appellants further note that the arguments provided hereinbelow apply separately to each of claims 1, 8, 9 and 17-19. Thus, claims 1, 8, 9 and 17-19 do not stand together but stand separately.

7.1 THE LEGAL STANDARD FOR ANTICIPATION

7.1.1 Single prior art document must teach all elements of the claimed invention

As noted in M.P.E.P. §706.02(a) "for anticipation under 35 U.S.C. 102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present" (emphasis added).

7.1.2 Anticipation rejection based on inherency requires missing descriptive material to be necessarily present in the matter described in the prior art reference

With regard to inherent anticipation, "[t]he fact that a certain result or characteristic may occur or be present in

the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)", as cited in M.P.E.P. §2112. More specifically, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.*' In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)" (M.P.E.P. §2112) (emphasis added).

7.1.3 The prior art document must provide an enabling disclosure for what it allegedly teaches

The M.P.E.P §2121.01 makes it clear that for a prior art reference to anticipate a claim the reference must contain an enabling disclosure for the anticipatory subject matter. "The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; *mere naming or description of the subject matter is insufficient*, if it cannot be produced without undue experimentation. Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003)" (emphasis added).

7.2 XU ET AL. DOES NOT TEACH EVERY ASPECT OF APPELLANTS' CLAIMED INVENTION

7.2.1. *Examiner's Characterization of prior art reference Xu et al.*

(Initially, Appellants note that it has been agreed that sFRP-5 peptide is the same as SARP3).

The Examiner alleged on pages 11 and 12 of the Office Action issued April 19, 2006 in connection with the above-identified application (as cited by the Examiner in the January 10, 2007 Final Office Action and in the April 16, 2007 Advisory Action) that Xu et al. teaches "administration of a polypeptide SARP of SEQ ID NO:2 which is 100% identical to the polypeptide of SEQ ID NO:1 (appendix-A) of the instant application for the treatment of metabolic disorders including obesity and diabetes comprising the SARPs polypeptides...." The Examiner further stated that Xu et al. "do not explicitly teach reduction in an amount of adipose tissue but the administration of the polypeptide of SEQ ID NO:2 or a variant would inherently achieve the same effect in a subject as instantly being claimed...."

7.2.2. *Xu et al. does not teach all the elements of the claimed invention.*

Claim 1, and claims 8 and 9 dependent therefrom, require that the subject be administered (i) an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or (ii) an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject. Xu et al. however, does not teach either of these. Instead Xu et al. discusses administering an SARP3 "modulator".

Importantly there is no teaching in Xu et al. of what the "modulator should do; no teaching whatsoever of whether the modulator should inhibit SFRP-5 or induce SFRP-5 or activate SFRP-5 production. This information is not in Xu et al.

Thus, in rejecting claims 1, 8 and 9, appellants note that the Examiner has not properly applied the law of anticipation. The same argument applies mutatis mutandis to the subject matter of claims 17-19.

Xu et al. does not teach what "modulating" SARP3 means. Although the Examiner states in the Advisory Action issued April 16, 2007 in connection with the above-identified application that Xu et al. "interpret the term 'modulate' as either to stimulate or to inhibit (see-[0041]" this is not factually correct. What paragraph [0041] of Xu et al. actually states is "..to modulate (***e.g.***, stimulate or inhibit) the activity of the SARP3 polypeptide" (emphasis added). Thus, Xu et al. provide two examples of what modulate might mean.

Clearly, the Examiner's binary interpretation of "modulate" as used by Xu et al. to mean either stimulate or inhibit is not warranted in view of the exemplification language clearly implying other encompassed embodiments. Appellants suggest, merely for the sake of argument, that other such embodiments of "modulate" might be making the activity of the SARP3 polypeptide preferentially sensitive to one compound in favor of another etc. In any event, "modulate activity of" cannot be read as synonymous with "stimulate expression of" as is required for the Examiner's anticipation rejection to be proper. The interpretation of modulate as stimulate is merely one possibility selected by the Examiner to reject appellants'

invention, and cannot be the basis of a proper anticipation rejection.

It is appellants position that Xu et al. does not explicitly teach all the elements of appellants' invention as claimed in claims 1, 8, 9, and 17-19.

7.3 MISSING DESCRIPTIVE MATERIAL NOT NECESSARILY PRESENT IN XU ET AL.

7.3.1 An anticipation rejection relying on inherency is not proper unless "the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill", M.P.E.P. §2112, as cited above. In fact inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient", M.P.E.P. §2112, as cited above. Thus for the Examiner's rejection of claim 1 (and claims 8 & 9) as based on inherency to be proper the modulatory amount of SARP3 discussed in Xu et al. *must necessarily* also be an amount effective to reduce the amount of adipose or an amount effective to stimulate expression of the sFRP-5 peptide in the subject. Similarly, for the Examiner's rejection of claim 17 (and claims 18 & 19) as based on inherency to be proper the modulatory amount of SARP3 discussed in Xu et al. must necessarily also be an amount effective to reduce the level of adipocyte formation or an amount effective to stimulate expression of the sFRP-5 peptide in the subject. Appellants note that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic

necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added).

Xu et al. does not teach anything which could inherently result in the claimed invention. Xu et al. does not teach either (a) administering to a subject an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue or (b) administering to a subject or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject as recited in claims 1, 8 or 9. In addition, appellants maintain that Xu et al. does not explicitly or inherently teach (a) administering to a subject an amount of an sFRP-5 peptide effective to reduce the formation of adipose tissue or (b) administering to a subject or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject as recited in claims 17, 18 or 19.

Appellants further note that the Examiner has not put forth any evidence demonstrating that the unstated elements in the prior art were ever present. Rather, the Examiner has relied on a statement of a guess in a patent application to conclude that the prior art must inherently disclose all of the elements of the claims. However, claims cannot be inherently anticipated if the prior art fails to disclose, and is not capable of inherently disclosing, all of the elements of the claims. *See Application of Seaborg*, 328 F.2d 996 (C.C.P.A. 1964).

The case of *Application of Glenn T. Seaborg* is illustrative of this point. In *Seaborg*, the applicant sought to patent atomic element 95. The patent office relied on a prior art patent disclosing a nuclear reactor and a theoretical formula which

predicted that the claimed element would be produced by running the reactor. *Id.* at 996-97. The Court of Customs and Patent Appeals reversed this rejection, holding that there was no positive evidence that the claimed element was inherently produced by running the nuclear reaction. *Id.* at 999.

In this case, the Examiner has relied on a guess stated in a patent application, not even an experiment. Like in *Seaborg*, the Examiner has chosen one convenient speculation from the prior art. Such hindsight selection based on speculation is not sufficient to reject a claim under the doctrine of inherent anticipation.

Appellants note with regard to this point that, in *Perricone v. Medicis Pharmaceutical Corporation*, a district court held a method claim for treating a sunburn by applying a specific compound to the affected area to be inherently anticipated by prior art disclosing compound for "topical application" to the skin. On appeal, however, the Federal Circuit reversed the finding of invalidity and determined that the prior art did not anticipate this claim because "the district court's inherency analysis goes astray because it assumes what [the prior art] neither disclosed nor rendered inherent" as the prior art did not disclose applying the compound to skin sunburn. *Perricone v. Medicis Pharmaceutical Corporation*, 432 F.3d 1368, 1378 (Fed. Cir. 2005). It is irrelevant that the prior art compound *may* have been applied to sunburned skin. *Id.* At 1379.

Because Xu et al. does not teach actual administration of the "modulator" nothing can occur in Xu et al., either literally or inherently.

7.4 XU ET AL. IS NOT AN ENABLING DISCLOSURE FOR THE ALLEGEDLY ANTICIPATORY SUBJECT MATTER

7.4.1. *Appellants' position that Xu et al. is not an enabling disclosure for what the Examiner asserts it teaches.*

Appellants note that for the anticipation rejection (either explicit or inherent) of the pending claims to be proper, Xu et al. must be enabling for what the Examiner alleged it teaches. Appellants further note that the following paragraph is the description in Xu et al. that the Examiner impliedly asserts is an enabling disclosure:

> In yet another aspect, the invention features a method for treating a subject having a metabolic disorder characterized by aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia, or cachexia. The method includes administering to the subject a SARP3 modulator, e.g., in a pharmaceutically acceptable formulation or by using a gene therapy vector. Embodiments of this aspect of the invention include the SARP3 modulator being a small molecule, an anti-SARP3 antibody, a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO:2 or 5 or a fragment thereof, a SARP3 polypeptide comprising an amino acid sequence which is at least 90 percent identical to the amino acid sequence of SEQ ID NO:2 or 5, an isolated naturally occurring allelic variant of a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or 5, an antisense SARP3 nucleic acid molecule, a nucleic acid molecule of SEQ ID NO: 1, 3, 4, or 6 or a fragment thereof, or a ribozyme.

Appellants note, however, that "mere naming or description of the subject matter is insufficient, if it cannot be produced without *undue experimentation*. Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research, 346 F.3d 1051, 1054, 68

USPQ2d 1373, 1376 (Fed. Cir. 2003)", (emphasis added). M.P.E.P §2121.01. Appellants note that the claimed invention is based on the appellants' discovery of reduction in weight in two of the three independent lines of sFRP-5 transgenic mice, produced by appellants, which overexpress the sFRP-5 polypeptide (see page 21, lines 29 to 31), none of which is described in Xu et al. Appellants maintain that the minimal description in Xu et al. as relied upon for the anticipation rejection of the pending claims is insufficient to be an enabling disclosure, especially in light of the experimental results.

Furthermore, the same Examiner has previously acknowledged that the disclosure of Xu et al. is not enabling "for a method of modulating a SARP3 mediated lipid metabolism" (see Examiner's comments on page 6 of the Office Action issued May 16, 2006 (**Evidence Appendix Exhibit B.2**) in connection with U.S. Serial No. 10/338,604, of which the cited Xu et al. is the U.S. Patent Application Publication). More pertinently, on page 9 of the same document, the Examiner stated that to practice a method of modulating a SARP3-mediated activity comprising contacting a cell or tissue that expresses SARP3 with a SARP3 modulator that can modulate lipid metabolism "it would require *undue experimentation* by one of skill in the art to be able to practice the claimed invention" (emphasis added). Such a disclosure is thus clearly not enabling for modulating a SARP3-mediated activity.

"To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are

not enabled" *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (internal citations omitted). A reference is enabling "if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985).

Courts have refused to find anticipation based on prior art that is not enabling. For instance, in *Rockwell Intern. Corp v. U.S.*, the Federal Circuit refused to invalidate patent claims based on prior art which did not "provide sufficient basic chemistry information to enable one skilled in the art to grow epitaxial . . . semiconductors" (i.e. practice the claimed process). *See Rockwell Intern. Corp v. U.S.*, 147 F.3d 1358, 1364 (Fed. Cir. 1998). Likewise, in *Application of Sheppard*, the Court of Customs and Patent Appeals held that a prior art reference which disclosed either the claimed compound *or* a different compound was not enabling and therefore could not anticipate the claim at issue. *Application of Sheppard*, 339 F.2d 238, 241-242 (C.C.P.A., 1964).

In the present case, the Examiner has cited prior art speculating on both the selection of a process and the result of such process. Such prior art, like the prior art in *Rockwell* and *Sheppard*, does not enable one skilled in the art to practice the claimed process. Accordingly, this prior art does not anticipate the claims in the present application.

Appellants maintain that the anticipation rejection, either express or inherent, based on Xu et al. is improper and must be withdrawn.

7.5 SUMMARY

For the foregoing reasons, Appellants submit that the Examiner's rejections of claims 1, 8-9 and 17-19 are erroneous, and respectfully submit that the rejections of these claims should be reversed.

Respectfully submitted,

Gary J. Gershik

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Gary J. Gershik 2/5/09

Gary J Gershik Date
Reg. No. 39,992

CLAIMS APPENDIX

EXHIBIT A-1

1. A method of reducing the amount of adipose tissue in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide compromises consecutive amino acids having the sequence set forth in SEO ID NO: 1.

8. The method of claim 1, wherein the subject is human.

9. The method of claim 1, wherein the administration is parenteral, intradermal, transdermal, transmucosal, rectal, subcutaneous, or by inhalation.

17. A method of reducing the level of adipose tissue formation in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the level of adipose tissue formation, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide comprises consecutive amino acids having the sequence set forth in SEO ID NO: 1.

18. The method of claim 17, wherein the subject is human.

19. The method of claim 17, wherein the administration is parenteral, intradermal, transdermal, transmucosal, rectal, subcutaneous, or by inhalation.

EXHIBIT B

EVIDENCE APPENDIX

B.1 U.S. Patent Application Publication No. 2003/0143610 A1, published July 31, 2003

B.2 Office Action issued May 16, 2006 in connection with U.S. Serial NO. 10/338,604

B.3 Statement of where B.1 and B.2 were entered into the record by the Examiner

EXHIBIT B-1

US 20030143610A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2003/0143610 A1**

(43) **Pub. Date: Jul. 31, 2003**

Xu

(54) **METHODS FOR THE TREATMENT OF METABOLIC DISORDERS, INCLUDING OBESITY AND DIABETES**

(75) Inventor: **Haiyan Xu**, Weymouth, MA (US)

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(73) Assignee: **Millennium Pharmaceuticals, Inc.**

(21) Appl. No.: **10/338,604**

(22) Filed: **Jan. 8, 2003**

Related U.S. Application Data

(60) Provisional application No. 60/346,523, filed on Jan. 8, 2002.

Publication Classification

(51) Int. Cl.[7] A61K 48/00; A61K 31/00; C12Q 1/68; A61K 39/395

(52) U.S. Cl. 435/6; 424/143.1; 514/1; 514/44

(57) **ABSTRACT**

The invention relates to methods and compositions for the diagnosis and treatment of metabolic disorders, including, but not limited to, obesity, diabetes, overweight, insulin resistance, anorexia, and cachexia. The invention further provides methods for identifying a compound capable of treating a metabolic disorder. The invention also provides methods for identifying a compound capable of modulating a metabolic activity. Yet further, the invention provides a method for modulating a metabolic activity. In addition, the invention provides a method for treating a subject having a metabolic disorder characterized by aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression. In another aspect, the invention provides methods for modulating lipogenesis in a subject and methods for modulating lipolysis in a subject.

EXHIBIT B-2

UNITED STATES PATENT AND TRADEMARK OFFICE

1

UNITED STATES DEPARTMENT OF COMMERCE
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Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/338,604	01/08/2003	Haiyan Xu	MFI01-2508RM	2687

32116 7590 05/16/2006

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/338,604	XU, HAIYAN	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2006*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 9-11 and species "the ability to modulate lipid metabolism" in the reply filed on 03/01/2006 is acknowledged. However, Applicant did not distinctly and specifically points out the supposed error in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

Claims 1-20 are pending. Claims 1-8, and 12-20 are withdrawn from further consideration as being drawn to a nonelected invention.

Claims 9-11 are examined on the merit to the extent that they read on the elected species the ability to modulate lipid metabolism.

Information Disclosure Statement

The information disclosure statement (IDS) filed on 4/15/2005 has been considered.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 59, lines 8 and 11. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 9 is objected for the use of many abbreviated phrases (SARP3), which should be described for the first time followed by an abbreviated form placed in a bracket. Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack a well established utility and must undergo extensive experimentation.

Specifically, claims 9-11 are directed to a method of modulating a SARP3 mediated activity comprising contacting a cell or a tissue that expresses SARP3 with a SARP3 modulator that can modulate lipid metabolism. However, the instant specification does not teach any significance or functional characteristics of the polypeptide SARP3. The specification also does not disclose any specific methods or

working examples for modulating lipid metabolism. The specification discloses in general how a skilled artisan can different screening methods to identify a compound for any known protein that has a known biological function, but fails to show if the instantly claimed polypeptide has any such an impact. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed polypeptide SARP3:

1) to prepare an antibody (pg 63-66);

2) to screen modulators of SARP3 activity (pg 8-20);

3) to detect metabolic disorders (page 20-28); and

4) to treat subjects suffering from metabolic disorders (pg 34-41)

Each of these shall be addressed in turn.

1) to prepare an antibody. This asserted utility is not specific or substantial. An antibody can be prepared for any protein and it is a routine in the art. Further, the specification discloses nothing specific or substantial for the SARP3 polypeptide where this antibody can be used. The use of an antibody for binding the protein against which it is raised is of the type of experimentation that does not meet the requirements of 35 USC § 101.

2) to screen modulators of SARP3. This asserted utility is not specific or substantial. The specification discloses methods to screen for a compound that can modulate a polypeptide SARP3 activity. Since the polypeptide itself does not have any

known activity, the methods of screening using the SARP3 are not presented in a ready to use, real-world application, and the asserted utility is not substantial.

3) to detect metabolic disorders. These asserted utilities are not substantial. The disclosed utility is not substantial because the specification provides no information that the polypeptide SARP3 can accomplish this. The specification teaches how one can use a marker to detect its presence in a sample. However, in the absence of any biological relevance or disease association, mere presence of the SARP3 polypeptide or mRNA encoding a SARP3 polypeptide does not provide a specific and substantial utility for detecting a metabolic disorder. Significant further research would be required of the skilled artisan to perform experiments to establish, if the protein or encoding nucleic acid could be used for detecting a metabolic disorder. Since the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

4) to treat subjects suffering from metabolic disorders. Since the polypeptide SARP3 does not have any disclosed biological function and it is expressed in adipose tissue in a mouse model (Example 2, page 68), this does not establish its biological role for any therapeutic intervention. The disclosed polypeptide is an orphan protein for which a real world biological function has yet to be identified. Therefore, treatment of a metabolic disorder using a SARP3 modulator does not have a substantial support. Also, Chang et al. (IDS, Human Mol. Gen 8: 575-583, 1999) disclose that SFRP5, also know as SARP3, is expressed in retinal pigment epithelium (RPE) and may have some role in

wnt signaling. Therefore, any biological relevance of the polypeptide is far from a well established use.

Therefore, the asserted utility of the instantly claimed invention is not established as a substantial and real-world use. Thus, the proposed use of the claimed method is simply a starting point for further research and investigation into potential uses of the polypeptide and any compound that would modulate its activity. See Brenner v. Manon, 148 U.S.P.Q. 689 (Sup. Ct, 1966), wherein the court held that.

Claims 9-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Even if the specification disclosed any utility for the claimed polypeptide, it would not enable for a method of modulating a SARP3 mediated lipid metabolism.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276

(CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986).

Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The Nature of the Invention: The claims are drawn to a method of modulating a SARP3 mediated activity comprising contacting a cell or a tissue that expresses SARP3 with a SARP3 modulator that can modulate lipid metabolism.

The state of the prior art and the predictability or lack thereof in the art:

Lipids and fatty acids play major role in energy balance, hormone synthesis and many metabolic activities. Ranneries et al. (Am. J. Physiology 274: E155- E161, 1998) suggest that any imbalance in fatty acid metabolism can lead to many diseases and disorders. They state that obesity develops due to an interaction between genetic

components and certain environmental factors such as a high fat diet (page E155, 1st paragraph of the left column). It is well known in the art that the low density lipid and triglycerides are high risk factors for many cardio-vascular diseases. Further, obesity is a risk factor for diabetes which is a polygenic disease. Chang et al disclose that the SFRP family comprise many proteins such as SFRP 1-5 (Table 1 on page 576) based on their structure homology. There is no suggestion if any of these proteins can modulate lipid metabolism. Rather Chang et al indicate a possible role of the claimed polypeptide in wnt signaling in eye retina. Therefore, the art indicates that SARP3 is not involved in lipid metabolism.

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability found in the art, detailed teachings are required to be present in the disclosure in order to enable the skilled artisan to practice the claimed invention. These teachings are absent. There is no discussion of how SARP3 can play a role in modulating lipid metabolism and thus, the specification fails to support the assertion of the therapeutic activities of the protein. One of skill in the art would have no starting point to determine how to modulate lipid metabolism. While the specification contains a general discussion on how to screen a compound that could bind or interact with a protein having a known biological function, the specification is totally devoid of any working example in which SARP3 is demonstrated to be involved in lipid metabolism so that it can be applied for treating diabetes or metabolic disorders in a diabetic subject for its contemplated use. The prior

art does not suggest or indicate that the instantly claimed polypeptide SARP3/SFRP5 has any role modulating lipid activity in a subject.

The breadth of the claims and the quantity of experimentation needed: Because the claims encompass a method of modulating a SARP3 mediated activity comprising contacting a cell or a tissue that expresses SARP3 with a SARP3 modulator that can modulate lipid metabolism, in the light of the teachings of the unpredictability found in the art discussed and because of the supra lack of sufficient teachings in applicants disclosure to overcome those teachings, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra, Ph.D.
Art Unit 1646
8 May 2006
Fax: 571-273-2922

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER

Notice of References Cited	Application/Control No. 10/338,604	Applicant(s)/Patent Under Reexamination XU, HAIYAN	
	Examiner Gyan Chandra	Art Unit 1646	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
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FOREIGN PATENT DOCUMENTS

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	N					
	O					
	P					
	Q					
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Ranneries et al., Am. J. Physiology 274: E155- E161, 1998.
	V	
	W	
	X	

copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
tes in MM-YYYY format are publication dates. Classifications may be US or foreign.

EXHIBIT B-3

Statement of where items B1 and B2 were entered into the record by the Examiner

Xu et al., U.S. Patent Application Publication No. 2003/0143610 A1, published July 31, 2003 (B1) was entered into the record by the Examiner in the Office Action issued April 19, 2006 in connection with the subject application.,

Office Action issued May 16, 2006 in connection with U.S. Serial No. 10/338,604 (B2) was acknowledged by the Examiner in the Advisory Action issued March 5, 2007 in connection with the above-identified application.

EXHIBIT C

69014-B

G

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

JANUARY 27, 2005

PTAS

102802699A

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1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

FEB 4

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THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

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RECORDATION DATE: 07/28/2004

REEL/FRAME: 015613/0506
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).
DOCKET NUMBER: 69014-B

ASSIGNOR:
CHADA, KIRAN K.

DOC DATE: 07/03/2003

ASSIGNOR:
CHOUINARD, ROLAND

DOC DATE: 07/03/2003

ASSIGNOR:
ASHAR, HENA

DOC DATE: 07/03/2003

ASSIGNOR:
SAYED, ABU

DOC DATE: 07/07/2004

ASSIGNEE:
HMGENE INC.
675 HOES LANE RESEARCH TOWER
ROOM R-603
PISCATAWAY, NEW JERSEY 08854

Applicants: Kiran K. Chada et al.
Serial No.: 10/768,566
Filed: January 29, 2004
Exhibit C

SERIAL NUMBER: 10768566
PATENT NUMBER:
FILING DATE: 01/29/2004
ISSUE DATE:
TITLE: METHOD OF TREATING OBESITY AND METABOLIC DISORDERS RELATED TO EXCESS ADIPOSE TISSUE BY ADMINISTRATION OF SFRP-5 PEPTIDE

PAULA MCCRAY, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

07-30-2004

102802699

Docket No. 69014-B

FORM PTO-1595 (Substitute) 7/28/04 RECORD P

(Rev. 8-98)

U.S. DEPARTMENT OF COMMERCE

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original document or copy thereof.

Patent and Trademark Office

1. Name of conveying party(ies):

Kiran K. Chada,
Roland Chouinard,
Hena Ashar and
Abu Sayed

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2. Name and address of receiving party(ies):

Name: HMGene Inc.

Internal Address:

Street Address: 675 Hoes Lane Research Tower
Room R-603

City/State/Zip: Piscataway, NJ 08854

Additional name(s) & address(es) attached? ☐ Yes ☒ No

3. Nature of Conveyance:

☒ Assignment ☐ Merger
☐ Security Assignment ☐ Change of Name
☐ Other

Execution Date(s): July 3, 2003; July 3, 2003; July 3, 2003; July 7, 2004

4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date(s) of the application is (are):

A. Patent Application No.(s) U.S. Serial No. 10/768,566, filed January 29, 2004

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

OPP/FINANCE 2004 JUL 23 AM 7:23

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Gary J. Gershik

Internal Address:

Street Address: Cooper & Dunham LLP
1185 Avenue of the Americas

City/State/Zip: New York, New York 10036

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR §3.41):.....$ 40.00

☐ Enclosed

☒ Authorized to be charged to deposit account

8. Deposit account number:

03-3125

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9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Gary J. Gershik
Name of Person Signing

Gary J. Gershik
Signature Reg. No. 39,992

July 23, 2004
Date

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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69014-B/GJG

Assignment

In consideration of One Dollar ($1.00), and other good and valuable considerations, the receipt of which is hereby acknowledged, we, the undersigned,

Kiran K. Chada residing at 116 Pinehurst Avenue, Apt. G22, New York, NY 10033;
Roland Chouinard residing at 164-B Pleasantview Drive, Piscataway, NJ 08854;
Hena Ashar residing at 239 W. Prescott, Edison, NJ 08820 and
Md. Abu Sayed residing at 1669 Spring Park Walk, Cincinnati, OH 45215

Hereby sell, assign and transfer to HMGene, Inc.

a corporation of the State of Delaware having a place of business at 675 Hoes Lane NJ 08854 in the County of Research Tower, Room R-603 and State of New Jersey

its successors, assigns and legal representatives, the entire right, title and interest for all countries, in and to any and all inventions which are disclosed and claimed, and any and all inventions which are disclosed but not claimed, in the application for United States Patent, which has been executed by the undersigned on July 3, 2003; July 3, 2003; July 3, 2003; July 7, 2004 and is entitled

METHODS OF TREATING OBESITY AND METABOLIC DISORDERS RELATED TO EXCESS ADIPOSE TISSUE BY ADMINISTRATON OF s-FRP-5 PEPTIDE
(U.S. Serial No. 10/768,566 , filed January 29, 2004, continuation-in-part of U.S. Serial No. 10/630,423, filed July 29, 2003, claiming benefit of U.S. Provisional Application No. 60/478,206, filed June 12, 2003 and U.S. Provisional Application No. 60/398,785, filed July 29, 2002)

and in and to said application and all divisional, continuing, substitute, renewal, reissue, and all other applications for U.S. letters Patent or other related property rights in any and all foreign countries which have been or shall be filed on any of said inventions disclosed in said application; and in and to all original and reissued patents or related foreign documents which have been or shall be issued on said inventions;

Authorize and request the Commissioner of Patents of the United States to issue to said Assignee, the corporation above named, its successors, assigns and legal representatives, in accordance with this assignment, any and all United States Letters Patent on said inventions or any of them disclosed in said application;

Agree that said Assignee may apply for and receive foreign Letters Patent or rights of any other kind for said inventions, or any of them; and may claim, in applications for said foreign Letters Patent or other rights, the priority of the aforesaid United States patent application under the provisions of the International Convention of 1883 and later modifications thereof, under the Patent Cooperation Treaty, under the European Patent Convention or under any other available international agreement; and that, when requested, without charge to, but at the expense of, said Assignee, its successors, assigns and legal representatives, to carry out in good faith the intent and purpose of this assignment, the undersigned or the undersigned's executors or administrators will, for the United States and all foreign countries, execute all divisional, continuing, substitute, renewal, reissue, and all other patent applications or other documents on any and all said inventions; execute all rightful oaths, assignments, powers of attorney and other papers; communicate to said Assignee, its successors, assigns and representatives, all facts known and documents available to the undersigned relating to said inventions and the history thereof; testify in all legal proceedings; and generally do everything possible which said Assignee, its successors, assigns or representatives shall consider desirable for aiding in securing, maintaining and enforcing proper patent protection for said inventions and for vesting title to said inventions and all applications for patents or related foreign rights and all patents on said inventions, in said Assignee, its successors, assigns and legal representatives; and

Covenant with said Assignee, its successors, assigns and legal representatives that no assignment, grant, mortgage, license or other agreement affecting the rights and property herein conveyed has been made to others by the undersigned, and that full right to convey the same as herein expressed is possessed by the undersigned.

Date: 7/3 2003
Witness: Camille Vaughn [signature]
Camille Vaughn [printed name]
454 Lewis St., Somerset, NJ [address]
08873

Kiran K. Chada [L.S.]

Date: 7/3 2003
Witness: Camille Vaughn [signature]
Camille Vaughn [printed name]
454 Lewis St., Somerset, NJ [address]
08873

Roland Chouinard [L.S.]

Date: 7/3 2003

Witness: Camille Vaughn (signature)

Camille Vaughn (printed name)

454 Lewis St., Somerset, NJ (address)

08873

Hena Ashar [L.S.]

Hena Ashar

Date: July 7th 2004

Witness: Jared Smith (signature)

Jared Smith (printed name)

429 McAlpin Ave. #1 (address)

Cincinnati, OH 45220

Md. Abu Sayed [L.S.]

Md. Abu Sayed

EXHIBIT D

RELATED PROCEEDINGS APPENDIX

-NONE-